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10/815,115

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Darin G. Schaeffer

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT

PAPER NUMBER

3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/815,115 | Applicant(s) SCHAEFFER ET AL. | |
| | Examiner MELISSA RYCKMAN | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/3/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-51,55,56,57,60,62-65,69-71,74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud (U.S. Patent No. 6,258,117) and further in view of Smith (U.S. Patent No. 7,329,279).

Claims 48-50,57,62-64,71:

Camrud teaches an expandable stent comprising: a plurality of substantially cylindrical ring structures (14), wherein each ring structure extends completely around a circumference of the stent (Fig. 4B) and comprises at least one unit structure; and at least one flexible (col. 9, ll. 20) connector member (90) joining two of said ring structures when said stent is in an unexpanded state, said connector member comprising a first end joined to one ring structure and a second end joined to an adjacent ring structure

(Fig. 4B), wherein said at least one connector member is biodegradable (col. 8, ll. 56) along an entire length thereof between said first end and said second end and is adapted to biodegrade when said stent is in an expanded state so that said two ring structures become substantially disjoined.

Camrud does not teach the geometry as specified in the claim for the connector member, however Smith teaches said connector member being curved along a direction of a longitudinal axis of the stent (Smith, 14, Fig. 1) and extending across a space separating adjacent ring structures. It would have been obvious to one of ordinary skill in the art to use the shape (U or V shape) of the connector member of Smith with the device of Camrud, as the bent shape provides greater flexibility when in the unexpanded shape, thus helping to position the stent and aid in movement of the arteries.

Claim 51 and 65:

Camrud teaches the many materials as stated in the claims (col. 9, ll. 10-22).

Claim 55,69:

Camrud teaches said ring structures comprise a non-biodegradable base (col. 5, ll. 53-58) material and one of more biodegradable coating layers (col. 5, ll. 33,34).

Claim 56,70:

Camrud teaches said ring structures comprise a base material made of a combination of non-biodegradable materials and biodegradable polymers (col. 5, ll. 53-58).

Claims 60,74:

Camrud teaches when said stent is in an unexpanded state there are two or more connector members (90) joining said two ring structures and adjacent connector members are circumferentially aligned (Fig. 5A).

Claims 52-54, 58,59,61,66-68,72,73,75,76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud (U.S. Patent No. 6,258,117) and (U.S. Patent No. 7,329,279) as applied to claims 48 and 50 above, and further in view of Kocur (U.S. Patent No. 6,350,277).

Claim 52,66,61,75,76:

Camrud and Smith disclose the claimed invention including the biodegradation takes place over time (Camrud, claim 15) but fails to teach explicitly 30-180 days, however Kocur teaches at least one connector member (115) is adapted to biodegrade within thirty days to one-hundred eighty days after said stent is expanded (col. 7, ll. 56). It would have been obvious to one of ordinary skill in the art to have the stent connector biodegrade in 30-180 days as this may be suitable for certain applications, such as aid regarding tumors, as discussed in Kocur, col. 8, ll. 5-8.

Claims 53,67:

Camrud and Smith disclose the claimed invention but fail to teach multiple layers, however Kocur teaches at least one connector member (115) comprises a multitude of layers each having varying degradation rates (col. 7, ll. 18,57-60, varying thickness is inherently varying degradation rate). It would have been obvious to one of ordinary skill

in the art to have a varying degradation rate as this would cause a smoother transition for the adjacent body lumen.

Claims 54,68:

Camrud and Smith disclose the claimed invention but fail to teach the connector member has one layer with a uniform degradation rate, however Kocur teaches at least one connector member (115) comprises one layer having a substantially uniform degradation rate (col. 7, ll. 55-57). It would have been obvious to one of ordinary skill in the art to have a uniform degradation rate as this provides a smoother transition for the adjacent vasculature.

Claims 58,59,72,73,61,75,76:

Camrud and Smith teach the claimed invention, but do not teach the geometries as taught in the claims, however Kocur teaches at least one unit structure (Kocur, 125) comprises a plurality of strut members (Kocur, 120) and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern (Kocur, Fig. 1), said first end is connected to one of said plurality of bends (Kocur, Fig. 1) of said one ring structure and said second end is connected to another of said plurality of bends of said adjacent ring structure (Kocur, Fig. 1). It would have been obvious to one of ordinary skill in the art to use the geometries as taught by Kocur as this has proved common and successful in the art, as this geometry is commonly known to provide greater flexibility of the stent.

Response to Arguments

Applicant's arguments with respect to all the claim have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

Application/Control Number: 10/815,115
Art Unit: 3773

Page 7

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773